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1619

Docket No. 13761-7065

Certificate of Mailing/Transmission (37 C.F.R. § 1.8(a)):

[X] Pursuant to 37 C.F.R. § 1.8, I hereby certify that this paper and all enclosures are being deposited with the United States Postal Service as first class mail on the date indicated below in an envelope addressed to the Assistant Commissioner for Patents, Washington D.C. 20231.

[ ] Pursuant to 37 C.F.R. § 1.6(d), I hereby certify that this paper and all enclosures are being sent via facsimile on the date indicated below to the attention of Examiner _____ at Facsimile No. _____ at ____a.m./p.m.

Dated: July 1, 2002 Name of Person Certifying: Bernice E Worley
Printed Name: Bernice E. Worley

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Laurie DeLeve
Assignee: University of Southern California
Filing Date: February 27, 2002
Examiner: Not assigned
Serial No.: 10/086,072
Group Art Unit: 1619
Title: Composition and Method for Preventing and Treating Sinusoidal Obstruction Syndrome and Radiation-Induced Liver Disease

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Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. § 1.56, the references listed on the attached Form PTO-1449 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application.

I. Timing of the Information Disclosure Statement:

This Information Disclosure Statement is filed:

☐ With the new patent application submitted herewith (37 C.F.R. § 1.97(a)).

☐ Within three months after the filing date of the application or within three months after the date of entry of the national stage of a PCT application as set forth in 37 C.F.R. § 1.491.

☐ Before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114.

☒ Before the mailing of a first Office action on the merits. In the event, however, that an Office Action has crossed in the mail with this Information Disclosure Statement:

- ☒ the Commissioner is hereby authorized to charge Deposit Account No. 50-1192, Docket No. 13761-7065 for the fee ($180) set forth in 37 C.F.R. § 1.17(p) and any additional required fees.
- ☐ a statement as specified in 37 C.F.R. § 1.97(e) is provided below.

This Information Disclosure Statement is filed:

☐ After the first Office Action and more than three months after the application's filing date; or PCT national stage date of entry filing, or after the mailing of a first Office Action after the filing of a request for continued examination, but, as far as is known to the undersigned, prior to the mailing date of either a final rejection or a notice of allowance, whichever occurs first, and

- ☐ the Commissioner is hereby authorized to charge Deposit Account No. [ ] for the fee ($180) set forth in 37 C.F.R. § 1.17(p) and any additional required fees.
- ☐ a statement as specified in 37 C.F.R. § 1.97(e) is provided below.

This Information Disclosure Statement is filed:

☐ After the mailing date of either a final rejection or a notice of allowance, whichever occurred first, but on or before the payment of an issue fee, and is accompanied by the fee ($180.00) set forth in 37 C.F.R. § 1.17(i)(1) and a certification as specified in 37 C.F.R. § 1.97(e), as checked below. This document is to be considered as a petition requesting consideration of the Information Disclosure Statement.

Pursuant to 37 C.F.R. § 1.97(e), the undersigned certifies that:

☐ Each item of information contained in the Information Disclosure Statement was first cited in any communication mailed from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.

☐ No item of information contained in this information disclosure statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

II. Copies of the Cited Items:

☒ Copies of all of the items listed on the attached Form PTO-1449 are enclosed.

☐ Copies of only the following items listed on the attached Form PTO-1449 are enclosed: _____.

☐ Copies of those items which are marked with an asterisk (*) in the attached Form PTO-1499 are not supplied because they were previously cited by or submitted to the Patent Office in a prior Application No. _____, filed _____ and relied upon in this application for an earlier filing date under 35 U.S.C. § 120. See 37 C.F.R. § 1.98(d).

☐ Copies of those items which are marked with an asterisk (**) in the attached Form PTO-1499 were cited in a foreign examination report in a related case. A copy of the search report and the cited references not already of record in this application are attached hereto.

III. Concise Explanation of Relevance:

☒ A concise explanation of relevance of the items listed on Form PTO-1449 is not given.

☐ A concise explanation of relevance of [some of] the items listed on Form PTO-1449 is in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references (copy attached).

IV. Conclusion:

Citation of the above documents shall not be construed as:

1. an admission that the documents are necessarily prior art with respect to the instant invention;
2. a representation that a search has been made, other than as described above; or
3. an admission that the information cited herein is, or is considered to be, material to patentability as defined in § 1.56(b).

It is respectfully requested that the Examiner indicate consideration of the cited references by returning a copy of the attached form PTO 1449 with initials or other appropriate marks.

The Commissioner is hereby authorized to charge Deposit Account No. 50-1192 Docket No.: 13761-7065 for any additional fees required in connection with the filing of this Information Disclosure Statement.

DATE: July 1, 2002

Respectfully submitted,

By: Jennifer M. Phelps

Jennifer M. Phelps
Registration No.: 48,656

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FORM PTO-1449 (Modified [6-1])

LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT(S)' INFORMATION DISCLOSURE STATEMENT
(Use several sheets if necessary)

ATTY. DOCKET NO.	SERIAL NO.
13761-7065	10/086,072

TITLE
COMPOSITION AND METHOD FOR PREVENTING AND TREATING SINUSOIDAL OBSTRUCTION SYNDROME AND RADIATION-INDUCED LIVER DISEASE

INVENTOR
Deleve, Laurie

FILING DATE	GROUP ART UNIT
February 27, 2002	**1619**

REFERENCE DESIGNATION **U.S. PATENT DOCUMENTS**

EXAM'R INITIAL		DOCUMENT NUMBER	DATE	NAME	Class	Subclass	Filing Date If Appropriate
	A1.						
	A2.						
	A3.						
	A4.						

FOREIGN PATENT DOCUMENTS

EXAM'R INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	Subclass	TRANSLAT'N yes	TRANSLAT'N no
	B							
	B3							
	B2							
	B4							

OTHER ART (Include Author, Title, Date, Pertinent Pages, *etc.*)

	C1.	DeLeve LD, Shulman HM, McDonald GB. Toxic injury to hepatic sinusoids: sinusoidal obstruction syndrome (venoocclusive disease). Sem.Liver Dis. 2002;22(1):623-38.
	C2.	Rajvanshi P, Shulman HM, Sievers EL, McDonald GB. Hepatic sinusoidal obstruction following Gemtuzumab Ozogamicin (Mylotarg®). Blood 2002.
	C3.	DeLeve LD. Liver Function and Hepatotoxicity in Cancer. In: Holland JF, Frei E, Bast RC, Jr., Kufe DW, Pollock RE, Weichselbaum RR, editors. Cancer Medicine. 5th ed. Hamilton, Ontario, Canada: B.C. Decker Inc; 2000. p. Chapter 151.
	C4.	DeLeve LD. Dacarbazine toxicity in murine liver cells: a novel model of hepatic endothelial injury and glutathione defense. J.Pharmacol.Exp.Ther. 1994;268:1261-70.
	C5.	DeLeve LD, Wang X, Kuhlenkamp JF, Kaplowitz N. Toxicity of azathioprine and monocrotaline in murine sinusoidal endothelial cells and hepatocytes: the role of glutathione and relevance to hepatic venooclusive disease. Hepatology 1996;23:589-99.
	C6.	DeLeve LD. Cellular target of cyclophosphamide toxicity in the murine liver: role of glutathione and site of metabolic activation. Hepatology 1996;24:830-7.
	C7.	DeLeve LD, Ito Y, Machen NW, McCuskey MK, Wang X, McCuskey RS. Embolization by sinusoidal lining cells causes the congestion of hepatic venoocclusive disease. Gastroenterol. 2000;118:A2345.

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference c nsidered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance *and* not considered. Include copy of this form with next communication to Applicant(s).

FORM PTO-1449 (Modified [6-1])	ATTY. DOCKET NO.	SERIAL NO.
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT(S)' INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	13761-7065	10/086,072
TITLE **COMPOSITION AND METHOD FOR PREVENTING AND TREATING SINUSOIDAL OBSTRUCTION SYNDROME AND RADIATION-INDUCED LIVER DISEASE**	INVENTOR **Deleve, Laurie**	
	FILING DATE **February 27, 2002**	GROUP ART UNIT **1619**

	C8.	DeLeve LD, McCuskey RS, Wang X, Hu L, McCuskey MK, Epstein RB, et al. Characterization of a Reproducible Rat Model of Hepatic Veno-occlusive Disease. Hepatology 1999;29:1779-91.
	C9.	Wang X, Kanel GC, DeLeve LD. Support of sinusoidal endothelial cell glutathione prevents hepatic veno-occlusive disease in the rat. Hepatology 2000;31:428-34.
	C10.	DeLeve LD, Ito Y, Machen NW, McCuskey MK, McCuskey RS. Sinusoidal dissection and embolization blocks the hepatic microcirculation in hepatic venoocclusive disease. In: Hepatology; 1999; 1999. p. 574A.
	C11.	Upadhya AG, Harvey RP, Howard TK, Lowell JA, Shenoy S, Strasberg SM. Evidence of a role for matrix metalloproteinases in cold preservation injury of the liver in humans and in the rat. Hepatology 1997;26:922-8.
	C12.	DeLeve LD, Wang X, Tsai J, Kanel G, Tokes Z. Prevention of Hepatic Venooclusive Disease in the rat by inhibition of matrix metalloproteinases. Gastroenterol. 2001;120:A54.
	C13.	Lamé MW, Jones AD, Wilson DW, Dunston SK, Segall HJ. Protein targets of monocrotaline pyrrole in pulmonary artery endothelial cells. J.Biol.Chem. 2000;275(37):29091-9.
	C14.	Read, AE, Weisner RH, LaBrecquie DR, et al. Hepatic venocclusive disease associated with renal transplantation and azathiprine therapy. Ann Intern Med 1986;104:651-655.
	C15.	McDonald GB, Hinds MS, Fisher LB, et al. Venocclusive disease of the liver and multiorgan failure after bone marrow transplantation: a cohort study of 355 pateints. Ann Intern Med. 1993;118:255-267.
	C16.	Jones RJ, Lee KS, Berschorner WE, eta l. Veno-occlusive disease of the liver following bone marrow transplantation. Transplantation 1987;44:778-783.
	C17.	Carreras E, Bertz H, Arcese W, et al. Incidence and outcome of hepatic veno-occlusive disease after blood or marrow transplantation: a prospective cohort study of the European group for blood and marrow transplantation. Blood 1998;92:3599-3604.
	C18.	Shulman HM, McDonald GB, Matthews D, et al. An analysis of hepatic venocclusive disease and centrilobular hepatic degeneration following bone marrow transplantation. Gastroenterology 1980;79:1178-1191.

EXAMINER	DATE CONSIDERED

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FORM PTO-1449 (Modified [6-1])

LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT(S)' INFORMATION DISCLOSURE STATEMENT
(Use several sheets if necessary)

TITLE
COMPOSITION AND METHOD FOR PREVENTING AND TREATING SINUSOIDAL OBSTRUCTION SYNDROME AND RADIATION-INDUCED LIVER DISEASE

ATTY. DOCKET NO.	SERIAL NO.
13761-7065	10/086,072
INVENTOR: Deleve, Laurie	
FILING DATE: February 27, 2002	GROUP ART UNIT: 1619

	C19.	Strasser SI, McDonald SJ, Schoch HG, et al. Severe hepatocellular injury after hematopoietic cell transplant: incidence and etiology in 2136 consecutive patients [Abstract]. Hepatology 2000;32:299.
	C20.	Kikuchi K, Rudolph R, McDonald GB. Portal vein thrombosis after heatopoietic cell transplant: incidence, treatment, and outcome. Hepatology 2000; 32:405 (Abs).
	C21.	Carreras E. Granena A, Navasa M, et al. Transjugular liver biopsy in bone marrow transplantation. Bone Marrow Transplant 1993;11:21-26.
	C22.	McDonald GB, Sharma P, Matthews DE, et al. The clinical course of 53 patients with venocclusive disease of the liver after marrow transplantation. Transplantation 1985;36:603-608.
	C23.	Wingard JR, Mellits ED, Jones RJ, et al. Association of hepatic veno-occlusive disease with interstitial pneumonitis in bone marrow transplant receipients. Bone Marrow Transplant 1989;4:685-689.
	C24.	Zager RA, O'Quigley J, Zager BK, et al. Acute renal failure following bone marrow transplantation; A retrospective study of 272 patients. Am J Kidney Dis 1989;13:210-216.
	C25.	Bearman SI, Anderson GL, Mori M, et al. Venoocclusive disease of the liber: development of a model for predicting fatal outcome after marrow transplantation. J Clin Oncol 1993;11:1729-1736.
	C26.	Bearman SI, Lee JL, Baron AE, et al. Treatment of hepatic venocclusive disease with recombinant human tissue plasminogen activator and heparin in 42 marrow transplant patients. Blood 1997;89:1501-1506.
	C27.	Cai T, Fassina G, Morini M, et al. N-acetycysteine inhibits endothelial cell invasion and angiogenesis. Lab Invest 1999;79:1151-1159.
	C28.	Tyagi SC, Ratajska A, Weber KT. Myocardial matrix metalloproteinase(s): localization and activation. Mol Cell Biochem 1993;126;49-59.
	C29.	Tyagi SC, Kumar S, Borders S. Reduction-oxidation (redox) state regulation of extracellular matrix metalloproteinases and tissue inhibitors in cardiac normal and transformed fibroblast cells. J Cell Biochem 1996;61:139-151.
	C30.	Upadya GA, Strasberg SM. Glutathione, lactobionate, and histidine: cryptic inhibitors of matrix metalloproteinases contained in University of Wisconinsin and histidine/tryptophan/ketoglutarate liver preservation solutions. Hepatology 200;31:1115-1122.

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